IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Richmond Division

PATIENT SERVICES, INC.,

Plaintiff,

v. **Civil Action No. 3:18cv16**

UNITED STATES OF AMERICA, *et al.*,

Defendants.

MEMORANDUM OPINION

This matter comes before the Court on the Defendants'[1] Motion for Leave to Take Discovery (the "Motion"). (ECF No. 35.) Defendants request a limited discovery period to seek information on two issues: (1) whether Plaintiff Patient Services, Inc. ("Patient Services") waived its First Amendment constitutional right to engage in certain discussions with its donors, prospective donors, and their affiliates; and, (2) whether Patient Services suffered an actual harm, or injury-in-fact, from the issuance of a 2017 Advisory Opinion by the Office of the Inspector General of the Department of Health and Human Services ("HHS OIG"). Patient Services opposes the Motion to the extent Defendants seek discovery relating to the First

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[1] The Complaint names the following Defendants: the United States of America; Department of Health and Human Services ("HHS"); Officer of Inspector General ("HHS OIG"); Daniel R. Levinson, in his official capacity as Inspector General of the United States Department of Health and Human Services; and Eric D. Hargan, in his official capacity as Acting United States Secretary of the Department of Health and Human Services (collectively, "Defendants").

On January 29, 2018, Alex M. Azar II was sworn in as the Secretary of the Department of Health and Human Services. UNITED STATES DEP'T OF HEALTH AND HUMAN SERVS. *Alex M. Azar II*, https://www.hhs.gov/about/leadership/secretary/alex-m-azar/index.html (last accessed Oct. 14, 2018). Because Plaintiff Patient Services, Inc. ("Patient Services") named Acting Secretary Eric D. Hargan in his official capacity, the Court substitutes Azar for Hargan as the defendant in this case.

Amendment issue,[2] (Resp. Mot. 14–15, ECF No. 37), and Defendants replied, (ECF No. 38). Accordingly, this matter is ripe for disposition.

The Court dispenses with oral argument because the materials before it adequately present the facts and legal contentions, and argument would not aid the decisional process. The Court exercises jurisdiction pursuant to 28 U.S.C. § 1331.[3] For the reasons stated below, the Court will grant the motion, albeit on a limited basis.

I. Factual and Procedural Background

Each party before the Court presents itself as operating for the greater good. HHS OIG portrays itself as "an independent and objective oversight unit created to carry out the mission of preventing fraud and abuse and promoting [the] economy, efficiency, and effectiveness of HHS programs and operations." (Mem. Supp. Mot. 2, ECF No. 36.) It describes its work issuing written Advisory Opinions alongside the United States Department of Justice as "interpretation and application of certain statutory provisions designed to deter" fraudulent referral of medical goods and services to federal health care programs such as Medicare. (*Id.* 2.) HHS OIG seeks to assure that companies do not profit from steering products and services to federal healthcare programs when the companies' profit motivation might override best medical practices or fiscal integrity.

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[2] Regarding the second request for discovery, Patient Services offers to provide a "single, simple declaration" to establish "injury-in-fact for purposes of establishing Article III standing." (Resp. Mot. 14–15, ECF No. 37.) If the Court were to permit discovery as to Article III standing, Patient Services asks in the alternative that discovery be reciprocal.

[3] "The district courts shall have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States." 28 U.S.C. § 1331. Patient Services brings its Complaint pursuant to the First Amendment, U.S. CONST. amend. I, Section 702 of the Administrative Procedures Act ("APA"), 5 U.S.C. § 702, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202.

At the same time, Patient Services portrays itself as "a non-profit charitable foundation that operates Patient Assistant Programs ("PAPs"), which provide financial and other assistance to indigent patients who have chronic and often life threatening diseases that require expensive treatment and management." (Compl. ¶ 4, ECF No. 1.) Patient Services highlights that its founder and President, Dr. Dana Kuhn, not only suffers personally from hemophilia, but also founded Patient Services in 1989 after years of counseling patients and families through the physical, emotional, and financial strain of managing that chronic illness. Patient Services contends that since 1989, it has "provided financial assistance to hundreds of thousands of indigent patients." (Compl. ¶ 56.)

While the Motion pending before the Court makes a seemingly simple request—to grant a limited period of discovery—its resolution raises additional questions. Most importantly, the parties advocate for different First Amendment standards to apply: one that would allow limited discovery, and another that would not. The parties also disagree about how to supplement the Administrative Record to establish the harm necessary for Article III standing. Neither party suggests that supplementation as to harm should *not* occur.

For the reasons stated below, the Court will grant a limited period of discovery, followed by additional briefing to determine what (if any) discovered information will be used to supplement the Administrative Record the Court will consider in deciding Patient Services's Complaint.

A. Statutory and Regulatory Restrictions on How PAPs Can Operate

An introduction of the parties and the little-known regulatory scheme that binds them must precede consideration of the Motion. Because the regulatory scheme involves several laws and regulations governing a relatively unknown business practice, the Court sets forth a more

extensive overview than what it commonly would include. Indeed, the background seemingly overwhelms the Court's analysis.

First, the Court will describe the business model for entities, such as Patient Services, operating PAPs. Second, the Court will outline the provisions of the Social Security Act that necessitate HHS OIG's Advisory Opinions. Third, the Court will introduce the role HHS OIG plays in regulating the entities operating PAPs. Finally, the Court will examine the regulatory interaction between HHS OIG and Patient Services. Only then will the Court be able to address the Motion here.

1. The Business Model for PAPs and Patient Services in Particular

To assist indigent patients, PAPs, such as Patient Services, rely on donations from a variety of sources, "includ[ing] pharmaceutical manufacturers, disease treatment centers, hospitals and other healthcare facilities, disease specific charities, pharmacies, individual donors, and governmental entities such as the Commonwealth of Virginia."[4] (Compl. ¶ 70.) Indigent patients seeking aid from Patient Services, for instance, must provide "their (i) medical diagnosis and the type of assistance requested; (ii) demographic and contact information; (iii) income information; and[,] (iv) health insurance information." (*Id.* ¶ 60.) If approved for assistance, Patient Services may provide "assistance with health insurance premiums, travel expenses, copayment obligations, ancillary services, and infusion nursing services." (*Id.* ¶ 58.)

HHS determined that PAPs presented a heightened risk of "fraud, waste, and abuse with respect to Medicare and other [f]ederal heath care programs" in part because pharmaceutical manufacturers supported, and sometimes entirely sponsored, many PAPs. *See Suppl. Special*

[4] As a part of its business model, Patient Services divides its fund into specific "disease funds." (Compl. ¶ 70.) Donors "often earmark their contributions for specific disease funds." (*Id.* ¶ 72.) For instance, a donor "may donate money specifically to [Patient Services's] breast cancer screening fund or to [Patient Services's] Parkinson's disease fund." (*Id.*)

Advisory Bulletin: Independent Charity Patient Assistance Programs (the "2014 PAP Bulletin"), 79 Fed. Reg. 31120, 31120 (May 30, 2014). Observing this arrangement, HHS identified the possibility that PAPs might steer their charitable efforts to products their donors made or distributed. *Id.* HHS clarified that even PAPs such as Patient Services, who are not solely sponsored by a pharmaceutical manufacturer, might—but should not—operate as a conduit for improper payments involving federal healthcare programs, or impermissibly influence a beneficiary's drug choices. *See id.*

Having made these observations, HHS recognized that this potential improper conduct implicated penalty provisions in the Social Security Act. Because the Social Security Act imposes stiff penalties for any kickback or improper influence in business dealings that affect federal healthcare programs, a discussion of these two penalty provisions will follow. Only with that background can the Court turn to how Congress, through HHS OIG, decided to offer the option of regulatory protection to PAPs via Advisory Opinions.

2. The Social Security Act Imposes Criminal and Civil Penalties on Entities Operating Within the Federal Healthcare System That Improperly Steer Business to Donors

PAPs who accept donations from entities such as pharmaceutical companies or doctors who might, even indirectly, suggest self-dealing must be cautious of running afoul of two provisions in the Social Security Act. First, the Social Security Act's so-called "Anti-Kickback Statute" makes it a criminal offense to knowingly and willfully solicit, receive, offer, or pay any remuneration for business reimbursable by any federal healthcare program, such as Medicare, or

to induce or reward the referral or generation of business reimbursable by these healthcare programs.[5] 42 U.S.C. § 1320-7b(b).

A second provision of the Social Security Act, 42 U.S.C. § 1320a-7a(5), (the "Civil Penalty Statute") imposes civil monetary penalties on persons or entities who offer or transfer remuneration to any medical beneficiary when that remuneration is intended to influence which treatment provider or which particular treatment a beneficiary receives under Medicare or a comparable program. Because PAPs seek donations from entities which could profit from federal healthcare programs if the beneficiary chose to use their hospital, doctor, product, procedure, or prescription and the beneficiary relied on PAP funds to pay for the hospital, doctor, product, procedure, or prescription, these laws seek to curtail incentives for PAPs to steer business toward their donors.[6] They also seek to ensure that healthcare providers make decisions

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[5] The Anti-Kickback Statute applies both to receiving remuneration for referral of business that implicates a federal healthcare program and to offering or paying remuneration for inducing the referral of business to a federal healthcare program. 42 U.S.C. §§ 1320a-7b(b)(1)–7b(b)(2). It defines the receipt, offer, or payment of remuneration under these circumstances as a felony subject to a maximum 10 years imprisonment, a $100,000 fine, or both. *Id.*

[6] A concrete example best explains congressional wariness, and charities that provide co-payment assistance serve as the simplest example of how fraud or abuse might occur. For instance, if one year's supply of an experimental drug cost $100,000, but a patient could not afford the $5,000 co-pay before insurance (such as Medicare) would begin coverage, the patient might not receive the experimental drug.

But if a PAP paid the $5,000 co-pay, then a federal health program (such as Medicare) might become obligated to pay the $95,000 differential in the annual price of the experimental drug. If the PAP's $5,000 co-pay payment results in the patient qualifying for Medicare, the patient would receive the drug, and the pharmaceutical company would receive the remaining $95,000 cost of the medicine from the federal healthcare program.

This practice could be problematic if the pharmaceutical company (which may have already received a tax deduction for its contribution to the PAP) also stands as the primary or sole donor of the PAP. Specifically, if a PAP were to steer its co-pay donations toward treatment for a disease that can be alleviated by the experimental drug manufactured by its primary donor or its donor's affiliates, the pharmaceutical company might profit (in this instance by $ 95,000) from an abusive scheme. The risk would be especially high when only one pharmaceutical company sponsored a PAP.

about the allocation of federal healthcare services with only legitimate concerns in mind, such as quality or cost.

These potential stiff penalties have not gone unnoticed. Congress mitigated the statutes' application to innocent behavior by devising a process through which HHS OIG could advise PAPs as to how they may operate within the law. The Court turns to the HHS OIG Advisory Opinion Process now, bringing it closer to the heart of the dispute at bar.

3. The Role of HHS OIG in Regulating PAPs Including Patient Services

HHS OIG seeks to minimize the risk of potential federal healthcare fraud, i.e. Medicare fraud, that could occur if PAPs, even indirectly, steer business to their donors. *See* 2014 PAP Bulletin at 31120 ("PAPs have long provided important safety net assistance . . . [but m]any PAPs . . . present a risk of fraud, waste, and abuse with respect to Medicare and other [f]ederal health care programs.") Still, Congress recognized that the Social Security Act's Anti-Kickback and Civil Penalty Statutes were broad enough to risk the imposition of criminal liability for "relatively innocuous commercial arrangements," so Congress created the Advisory Opinion process to allow PAPs to receive guidance from HHS OIG about the legality of their business structure.[7] *See* Medicare and State Health Care Programs: Fraud and Abuse; Issuance of Advisory Opinions by the OIG, 62 Fed. Reg. 7350; 7350 (proposed Feb. 19, 1997).

To buffer against these potentially harsh penalties, Congress authorizes the HHS OIG, in consultation with the Attorney General, to issue Advisory Opinions when PAPs themselves seek guidance from HHS OIG on "actual or proposed factual circumstances" of their operations that

[7] Congress also created "safe harbors," not at issue here, which "specify various payment and business practices which, although potentially capable of inducing referrals of business under the Medicare and State health care programs, would not be treated as criminal offenses under the" Anti-Kickback Statute or the Civil Penalty Statute. 62 Fed. Reg. at 7351. These "safe harbors" apply to certain "generalized, hypothetical arrangements" in contrast to Advisory Opinions, which pertain to a specific entity and a specific business arrangement. *See id.*

may implicate the Social Security Act. 42 C.F.R. § 1008.1. When asked by a PAP, HHS OIG provides guidance about the legal parameters the PAP must operate within so as not to violate the constraints of the Social Security Act.[8] *See* 42 U.S.C. § 1320a-7d(b)(1); 42 C.F.R. § 1008.1, *et seq.*; *see also* Medicare and State Health Care Programs: Fraud and Abuse; Issuance of Advisory Opinions by the OIG, 62 Fed. Reg. 7350; 7351–52.

HHS OIG's Advisory Opinion Process as to the 2017 Modified Advisory Opinion lies at the core of this case. Thus, this detailed backdrop must turn from the Social Security Act and HHS OIG to the specific Advisory Opinion and bulletins that affected Patient Services.

4. The Regulatory Interaction Between HHS OIG and Patient Services

To date, HHS OIG has issued two Advisory Opinions directly to Patient Services and at least two general PAP Bulletins, applicable to all entities operating PAPs.[9] Patient Services

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[8] These regulations also identify the subject matter upon which HHS OIG and others may issue Advisory Opinions, (such as what might constitute prohibited remuneration). *See* 42 C.F.R. § 1008.5.

[9] On April 4, 2002, OIG first issued an Advisory Opinion approving of the manner in which Patient Services operated its PAP. (Compl. Ex. A, the "2002 Advisory Opinion," 5, ECF No. 1-2.) Relevant here, HHS OIG opined that although Patient Services's design implicated both the Anti-Kickback Statute and the Civil Penalty Statute, it "would not constitute grounds for the imposition of civil monetary penalties[,]" and OIG "would not seek to impose administrative sanctions." (2002 Advisory Opinion 5.) HHS OIG added that it reserved the right to reconsider the 2002 Advisory Opinion and, "where the public interest requires, to rescind, modify, or terminate [the] [O]pinion." (*Id.* 8.)

In 2003 Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which created Medicare Part D, "an optional prescription drug benefit . . . which went into effect in 2006." *See* Centers for Medicare & Medicaid Services, *History*, CMS.gov (last accessed Oct. 17, 2018), https://www.cms.gov/About-CMS/Agency-Information/History/index.html. Two general HHS advisory bulletins, applicable to all PAPs, ensued.

HHS OIG released the first PAP Bulletin in 2005, before Medicare Part D took effect. *Publ'n of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees*, (the "2005 PAP Bulletin"), 70 Fed. Reg. 70623 (Nov. 22, 2005). That 2005 PAP Bulletin provided guidance, in anticipation of Medicare Part D taking effect in 2006, to entities operating PAPs. *Id.* at 70624. HHS OIG issued an updated PAP Bulletin in 2014. 2014 PAP Bulletin, 79 Fed. Reg. 31120. The 2014 PAP Bulletin evaluated the impact of Medicare Part D

challenges the second and most recent Advisory Opinion, issued on March 3, 2017, (the "2017 Modified Advisory Opinion") as infringing on its First Amendment rights. Because the 2017 Modified Advisory Opinion flowed from information in the 2014 PAP Bulletin, the Court offers more information about both.

a. The 2014 PAP Bulletin Discussing the Effect of Medicare Part D Implicated the 2002 Advisory Opinion HHS OIG Issued to Patient Services

By way of background, the 2014 PAP Bulletin discussed the impact of Medicare Part D on the operation of all PAPs "based on experience [OIG had] gained in the intervening years" since 2006 when Medicare Part D had taken effect. 2014 PAP Bulletin at 31120. The 2014 PAP Bulletin identified two remunerative practices PAPs utilized that warranted increased scrutiny under the Anti-Kickback Statute. *Id.* at 31121. First, the 2014 PAP Bulletin identified those donations "made to a PAP to induce the PAP to recommend or arrange for the purchase of the donor's federally reimbursable items" as problematic. *Id.* Second, the 2014 PAP Bulletin recognized as troublesome those situations in which "a PAP's grant of financial assistance to a patient is made to influence the patient to purchase (or to induce the patient's physician to prescribe) certain items." *Id.* HHS recognized that this 2014 "amplifie[d]" industry-wide guidance might cause some previously-issued favorable Advisory Opinions to become inconsistent with the new guidance. *Id.* at 31123 ("We recognize that some charitable organizations with PAPs have received favorable [A]dvisory [O]pinions that may include features that are discouraged in" the 2014 PAP Bulletin.). HHS OIG stated that it would contact entities holding those favorable Advisory Opinions to modify them as necessary. *Id.* at 31123

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on the operation of PAPs during the eight years following the implementation of Medicare Part D. *See generally id.* Because it relates to the 2017 Modified Advisory Opinion, which HHS OIG issued directly to Patient Services and that stands at the heart of this dispute, the Court discusses the 2014 PAP Bulletin in more detail above.

("We are writing to all Independent Charity PAPs that have received favorable [O]pinions to explain how we intend to work with them to ensure that approved arrangements are consistent with our guidance. We anticipate that some [O]pinions will need to be modified.").

HHS OIG contacted Patient Services as one of the entities whose favorable Advisory Opinion, which it sought and received in 2002, might need modification. For seemingly more than two years,[10] the parties engaged in discussions to determine the scope of what would become the 2017 Modified Advisory Opinion. This back and forth resulted in the Administrative Record that will be filed in this case.[11]

Patient Services challenges three of the certifications it made in the 2017 Modified Advisory Opinion as infringing on its First Amendment rights. The Court creeps closer to the dispute at hand: the process in which the certifications became part of the 2017 Modified Advisory Opinion.

b. The 2017 Modified Advisory Opinion Referred to a Series of Certifications Made by Patient Services, Three of Which They Contend Violate the First Amendment

The 2017 Modified Advisory Opinion revised HHS OIG's prior favorable 2002 Advisory Opinion while delineating exceptions, listing modifications, and referring to certifications made

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[10] Patient Services contends that "OIG and [Patient Services's] discussed *over a period of several months* the modifications OIG was requiring." (Compl. ¶ 81 (emphasis added).) The timeframe alleged does not readily reconcile with the limited record before the Court. But even if the discussions occurred over "several months" rather than more than two years, as alleged by Defendants, (Mem. Supp. Mot. 6), the decision here would not change.

[11] In suits brought pursuant to the Administrative Procedure Act ("APA"), "the agency must produce an [A]dministrative [R]ecord that delineates the path by which it reached its decision." *Occidental Petroleum Corp. v. S.E.C.*, 873 F.2d 325, 338 (D.C. Cir 1989). Although Defendants have offered to file the Administrative Record for this case, the Court has not asked that it do so. While no disagreement appears to exist about the scope of the existing record, the parties strongly dispute whether the extant record should constitute the entirety of what this Court should consider.

by Patient Services.[12] Patient Services challenges three factual certifications, listed below, (collectively, the "Three Certifications"), as contrary to First Amendment principles. Patient Services seeks declaratory and injunctive relief to preclude the HHS OIG from enforcing the Three Certifications in the 2017 Modified Advisory Opinion because they impermissibly limit Patient Services's "truthful, non-misleading, and lawful communications with donors, prospective donors, and their 'affiliates.'" (Resp. 8, ECF No. 37; Compl. ¶¶ 129, 136, 143-44.)

First, Patient Services opposes the certification not to "solicit suggestions from donors regarding the identification or delineation of disease funds." (Compl. ¶ 89.)

Second, Patient Services contests the certification that "[n]o donor or affiliate of any donor [including a long list of what could be an affiliate] directly or indirectly influences or will influence the identification or delineation of any of the [c]harity's disease funds." (*Id.* ¶ 90.)

Third, and finally, Patient Services opposes the certification not to "establish or modify funds for specific diseases at the request or suggestion of donors or prospective donors (or affiliates of donors or prospective donors) that manufacture drugs or devices for treatment of such diseases or that otherwise have a financial interest in the establishment or modification of such funds." (*Id.* ¶ 91.)

With this extensive backdrop about Patient Services's business model, the regulatory scheme that resulted in the 2017 Modified Advisory Opinion, and the relationship between HHS OIG and Patient Services in place, the Court now turns to the Motion pending before it. But not without addressing two preliminary disputes.

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[12] Because they do not pertain to this matter, the Court omits discussion of the many other exceptions, modifications, and certifications in the 2017 Modified Advisory Opinion.

B. The Parties' Disagreement About Whether the Administrative Record Should be Expanded Requires Preliminary Resolution of Two Other Disputes

Neither party questions whether the speech at issue implicates the First Amendment: it does. But the Court must nevertheless address two contested issues before deciding whether the Administrative Record may be supplemented. First, the parties diverge as to whether this lengthy regulatory interaction resulted in a "negotiated" or "compulsory" set of findings. Because they dispute whether the administrative process involved a negotiation or the imposition of mandatory rules, a secondary question must be answered: which First Amendment standard applies? Each party asks the Court to apply a different analytical framework when evaluating this First Amendment challenge. The Court summarizes both Defendants and Patient Services's position below.

1. Defendants Contend That the Parties Negotiated the 2017 Modified Advisory Opinion so That the Fourth Circuit's *Lake James* Standard Applies

Defendants argue that their notice to Patient Services regarding the need to modify the 2002 Advisory Opinion "set off a lengthy negotiation process between OIG and [Patient Services], which lasted for more than two years." (Mem. Supp. Mot. 6.) HHS OIG posits that certain facts are subject to judicial notice. First, according to Defendants, Patient Services "was represented by sophisticated counsel throughout these negotiations." (Mem. Supp. Mot. 6 (citing Index to the Administrative Record 92–653, ECF No. 36-1)). Second, on February 1, 2017, before the 2017 Modified Advisory Opinion issued, Patient Services's "counsel sent OIG an executed list of the certifications with which [Patient Services's] would agree to conform its

conduct in accordance with the modification of its 2002 Advisory Opinion."[13] (*Id.* (citing Index to the Administrative Record 645–53)). This, Defendants say, evinces that a negotiation occurred.

Defendants concede that review of an agency decision under the Administrative Procedures Act (the "APA")[14] normally relies only on the administrative record submitted by the agency.[15] They add, however, that exceptions to doing so exist. Defendants contend that because Patient Services participated in negotiations that led to the 2017 Modified Advisory Opinion, an exception should apply here. This negotiation, according to Defendants, means that the Fourth Circuit's reasoning in *Lake James Community Volunteer Fire Department, Inc. v. Burke County*, 149 F.3d 277, 282 (4th Cir. 1998), governs the First Amendment dispute before the Court, even though the 2017 Modified Advisory Opinion "is not technically a contract."[16] (Mem. Supp. Mot. 10 n.2.)

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[13] It its Complaint, Patient Services alleges that, during these discussions, they raised not only the impracticality of the modifications, but also that they "would violate the First Amendment." (Compl. ¶ 81.) Defendants state that as part of the process leading to the 2017 Modified Advisory Opinion, Patient Services, "through a document signed by its then-CEO Dana Kuhn, made certain certifications in connection with the modification to its [A]dvisory [O]pinion." (Mem. Supp. Mot. 10.) Patient Services does not dispute that its CEO signed these certifications. Neither party identifies whether or not counsel for Patient Services or its CEO, signed any document subject to objection or disclaimer.

[14] Title 5, section 702 provides that "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702.

[15] Patient Services alleges that the 2017 Modified Advisory Opinion exists as "final agency action," reviewable under the APA. (Compl. ¶ 44.) The Court will assume, without deciding, that it evaluates a final agency action.

[16] Defendants argue that *Lake James* applies even though it clearly invoked a contractual dispute. The Fourth Circuit in *Lake James* upheld a negotiated waiver of the First Amendment right to bring suit contained in a negotiated contract between a Fire Department and the County in which it provided fire assistance services. *Lake James Community Fire Dep't, Inc. v. Burke Cty.*, 149 F.3d 277, 282 (4th Cir. 1998). In *Lake James*, the County required the contract with

Because the *Lake James* standard applies, Defendants contend that "the [A]dministrative [R]ecord lacks the necessary information" for the Court to decide Patient Services' claims. (Mem. Supp. Mot. 8.) Defendants seek information pertinent to the second prong of the *Lake James* test: whether Patient Services made a "knowing waiver" of its First Amendment rights. *Lake James*, 149 F.3d at 270. Defendants seek limited discovery to assess Patient Services's view of its interaction with HHS OIG during the years in which the parties discussed the 2017 Modified Advisory Opinion. Because the administrative record reflects only the agency's process, Defendants say it necessarily does not include Patient Services's view as to whether the Three Certifications were mandatory or negotiated.

Additionally, Defendants posit that Patient Services cannot establish injury-in-fact without adding information to the Administrative Record because any loss of donations occurred after the record closed. Patient Services appears to agree with this request to supplement the Administrative Record because it offers to provide a "single, simple declaration" to establish injury in fact.[17] (Resp. 14–15.) To establish harm, Defendants also seek evidence to determine

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the Fire Department to include two provisions which limited the Fire Department's ability to bring suit because the Fire Department had twice refused to perform its duties as required by its prior contracts. *Id.* at 279. Although the Fire Department argued that it was required to accept the provision even though it violated their First Amendment rights, the Fourth Circuit found that the Fire Department "entered into the contract . . . knowingly and intelligently; that it did so voluntarily;" and that the waiver did "not undermine the relevant public interests." *Id.* at 281.

Having determined that the contract was negotiated, the Fourth Circuit evaluated whether the Fire Department's waiver of its First Amendment rights was valid under a three-part test by asking if the waiver was: (1) a "knowing wavier," that was (2) "voluntarily given,"(3) which does "not undermine the relevant public interest." *Id.* at 280. The *Lake James* Court found that the waiver at issue there met each of these requirements. *Id.* at 281.

[17] Patient Services identifies a broad array of communications with donors, potential donors, or affiliates that it must have in order to establish a new disease fund:

> (i) the number of affected individuals; (ii) the demographics of the patient population; (iii) the cost of the new treatment or drug; (iv) the expected utilization

whether the communications in which Patient Services claims it may no longer participate in, "constituted 'lawful, truthful, and non-misleading communications.'"[18] (Mem. Supp. Mot. 12.) Without demonstrable harm, the Court would lack jurisdiction. Defendants seek discovery on this point as well.

2. Patient Services Contends That the Three Certifications Stemmed From an Agency Mandate, Meaning That the Supreme Court of the United States' First Amendment Commercial Speech Test Applies

Patient Services strongly disagrees that the 2017 Modified Advisory Opinion was negotiated, or that the *Lake James* standard should apply. Patient Services states that the HHS OIG "required" it to accept "nearly two dozen certifications," (Resp. Mot. 4), "as a condition for [Patient Services] to retain an [A]dvisory [O]pinion," (Resp. Mot. 13). It claims that the 2017 Modified Advisory Opinion "was a governmental mandate, not a voluntary request by [Patient Services]." (*Id.*) Patient Services counters that because the 2017 Modified Advisory Opinion is

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> of the drug; (v) coverage and other restrictions that payors are likely to impose, including government payors; (vi) the likely duration of likely therapy; (vii) how and where the drug or treatment will be administered (such as by a doctor in a hospital or by the patient in their own home); (viii) any ancillary patient needs such as transportation services; (ix) assistance for other supportive therapies that may be necessary; (x) the frequency and likelihood of complications or adverse events that can occur as a result of the treatment or drug; (xi) the costs associated with addressing side effects of the drugs or treatments; and (xii) whether any current donors or prospective donors have an interest in supporting this prospective new disease fund through donations.
>
> (Compl. ¶ 136.)

[18] Patient Services contends that Defendants "rather transparently, are attempting to convert [Patient Services's] challenge under the APA into an enforcement action in which Defendants can probe [Patient Services's] communications with donors, prospective donors, and their purported 'affiliates.'" (Resp. 3.) The Court cautions against any period of limited discovery becoming any kind of an enforcement action—and it is this subject matter which gives the Court greatest pause. Defendants shall confine their requests for discovery to that information necessary to assess any harm Patient Services suffered as a result of the 2017 Modified Advisory Opinion and what information the Court requires to assess Patient Services's challenge to the 2017 Modified Advisory Opinion.

not a contract, the Court should evaluate the 2017 Modified Advisory Opinion under general principals of the First Amendment.

Patient Services asserts that "OIG imposed the restrictions on [Patient Services]." (Resp. 13.) Patient Services suggests that this straightforward First Amendment dispute constitutes a matter of law subject to review under Supreme Court precedent governing its right to communicate with its donors. *See Sorrell v. IMS Health, Inc.*, 564 U.S. 552, 557 (2011) ("Speech in aid of pharmaceutical marketing . . . is a form of expression protected by the Free Speech Clause of the First Amendment.") Patient Services asserts that it must have these types of conversations with its donors, potential donors, and their affiliates who—because they are on the front lines of complicated expert medical research—are the only affordable source from which to make informed choices about establishing new disease funds and how best to modify those disease funds already in existence. Patient Services adds that "operating without an [A]dvisory [O]pinion is practically impossible" because many "donors and prospective donors, in particular pharmaceutical companies, will not donate to any PAP that does not operate pursuant to an [A]dvisory [O]pinion from [HHS] OIG."[19] (Compl. ¶ 45.)

As to harm, Patient Services alleges that the Three Certifications create a "brave new world of government censorship," (Compl. ¶ 6), which "hobble[s]" its ability to establish new disease funds, (Compl. ¶ 33). Patient Services adds that the "most likely result from these restrictions is that [Patient Services] will cease efforts to establish new disease funds and that donors . . . will not themselves have sufficient information about these funds to make donations."

[19] Patient Services claims that it cannot operate without an Advisory Opinion from HHS OIG. Defendants counter that "[t]he law does not require charities operating PAPs to obtain an advisory opinion from OIG. Indeed, [D]efendants are aware of at least one independent charity operating a PAP that does not have an advisory opinion." (Reply 7 n.2, ECF No. 38.) This disagreement does not alter this Court's decision.

(Compl. ¶ 118.) Patient Services alleges that it has already suffered an estimated "17% reduction in donations for its patient funds in 2018." (*Id.*)

Defendants seek limited discovery to probe the basis of the harm Patient Services alleges. In response to the request to probe the jurisdictional requisite of injury-in-fact, Patient Services offers to provide a "single, simple declaration" to establish "injury-in-fact for purposes of establishing Article III standing."[20] (Resp. 14–15.) Patient Services asks in the alternative that if the Court were to permit discovery as to Article III standing, that discovery be reciprocal. Clearly, either a declaration or discovery would expand the record beyond the extant Administrative Record.

C. Procedural History in This Court

On March 3, 2017, HHS OIG issued the 2017 Modified Advisory Opinion. (2017 Modified Advisory Opinion.) Approximately nine months later, on January 8, 2018, Patient Services filed this suit seeking declaratory and injunctive relief. On April 26, 2018, after the Court granted an extension of time, (ECF No. 22), Defendants filed their answer, (ECF No. 23).

On June 26, 2018, all parties attended an initial pretrial conference. During the initial pretrial conference, the parties raised their disagreement regarding the need for discovery in the case and the applicable First Amendment standard. The Court orally ordered that parties jointly prepare a briefing schedule on these issues, (Initial Pretrial Conf. Tr., ECF No. 34), and on July

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[20] Because a party must meet each of the requirements of Article III standing to assert a claim in federal court, the United States Court of Appeals for the District of Columbia Circuit recognized that "when the [A]dministrative [R]ecord fails to establish a substantial probability as to any element of standing, 'the petitioner must supplement the record to the extent necessary to explain and substantiate its entitlement to judicial review.'" *Grocery Mfrs. Ass'n v. E.P.A.*, 693 F.3d 169, 174 (D.C. Cir. 2012) (quoting *Sierra Club v. E.P.A.*, 292 F.3d 895, 899 (D.C. Cir. 2002)). Given Defendants' opposition to Patient Services's declaration taking the place of full discovery on the question of standing, the Court declines to merely consider the proffered declaration.

3, 2018, the parties jointly filed the proposed briefing schedule, (ECF No. 32), which the Court entered, (ECF No. 33). As agreed, Defendants filed a Motion for Leave to Take Discovery. Patient Services opposed the Motion and Defendants replied.

After unearthing these layers of factual, procedural, and regulatory events giving rise to the Motion, the Court may now finally turn to the issue on the surface: should the motion for discovery be granted, and, if so, to what degree?

II. Analysis

The ultimate outcome of this matter requires the interaction of three legal constructs: (1) the Social Security Act and the regulations creating the procedures by which HHS OIG may issue an Advisory Opinion; (2) the APA; and, (3) First Amendment jurisprudence. For purposes of the Motion, however, the Court need only address the APA. The parties agree that Patient Services brings its claims pursuant to Section 702 of the APA, 5 U.S.C. § 702,[21] and that APA rules regarding discovery differ from those in other federal civil actions.

A. Although Review Under the APA Normally Involves No Discovery, Courts Have Found Exceptions to This Rule

Federal Rule of Civil Procedure 26 grants a court broad discretion to order discovery. See Fed. R. Civ. P. 26(b)(1). Specifically, "[f]or good cause, the court may order discovery of any matter relevant to the subject matter involved in the action." *Id.* However, the APA limits a court's discretion to grant discovery when the court, as here, reviews the action of an administrative agency pursuant to the APA. *See, e.g., Camp v. Pitts*, 411 U.S. 138, 142 (1973);

[21] Section 706 of the APA defines the scope of this review, requiring, in relevant part, a reviewing court to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . [or] contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. §§ 706(2)(A)–(B). To make this determination, the statute requires the court to "review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error." 5 U.S.C. § 706.

Fort Sumter Tours, Inc. v. Babbitt, 66 F.3d 1324, 1335 (4th Cir. 1995). For the reasons stated below, and despite administrative procedural norms, the circumstances giving rise to the 2017 Modified Advisory Opinion convince the Court to permit a limited period of discovery.

The Supreme Court of the United States has stated that when reviewing agency action to assess arbitrariness, "the focal point for judicial review should be the [A]dministrative [R]ecord already in existence, not some new record made initially in the reviewing court." *Camp*, 411 U.S. at 142; *see Fort Sumter Tours, Inc.*, 66 F.3d at 1335 ("Judicial review of administrative action is generally confined to the administrative record" (citing *Fayetteville Area Chamber of Commerce v. Volpe,* 515 F.2d 1021, 1024 (4th Cir. 1975)). If the agency's finding "is not sustainable on the administrative record made, then the [agency's] decision must be vacated and the matter remanded to [them] for further consideration." *Camp*, 411 U.S. at 143. The Supreme Court has recognized that "[t]he task of the reviewing court is to apply the appropriate APA standard of review . . . to the agency decision based on the record the agency presents to the reviewing court." *Florida Power & Light Co. v. Lorion,* 470 U.S. 729, 743–44 (1985) (citing *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402 (1971)).

But courts have recognized a number of exceptions to the general rule that a reviewing court must make its determination based solely on the Administrative Record. Although the Fourth Circuit has not yet identified a list of these exceptional cases, the United States Court of Appeals for the District of Columbia Circuit and the United States Court of Appeals for the Ninth Circuit have done so.

For instance, the Ninth Circuit has identified four types of cases in which discovery may be warranted: (1) "when necessary to explain agency action," (2) "when serious gaps would frustrate challenges to the agency's actions," (3) "when it appears the agency has relied on

documents or materials not included in the record," and, (4) when "necessary to permit explanation or clarification of technical terms or subject matter involved in the agency action under review." *Pub. Power Council v. Johnson*, 674 F.2d 791, 793–95 (9th Cir. 1982)(citations omitted). Similarly, the D.C. Circuit rejected an attempt to expand on the Administrative Record with affidavits where the proffering party "ha[d] not demonstrated that the agency failed to examine all relevant factors or to adequately explain its grounds for decision, or that the agency acted in bad faith or engaged in improper behavior in reaching its decision." *IMS, P.C. v. Alvarez*, 129 F.3d 618, 624 (D.C. Cir. 1997).

A court in the United States District Court for the Eastern District of Virginia has also recognized two exceptions: (1) "in situations where 'those challenging agency action have contended the record was incomplete,'" *Tafas v. Dudas,* 530 F. Supp. 2d 786, 794 (E.D. Va. 2008) (quoting *Pub. Power Council*, 674 F.2d at 794), and, (2) "where there has been a 'strong showing of bad faith or improper behavior,'" *id.* at 797 (quoting *Cmty. For Creative Non-Violence v. Lujan*, 908 F.2d 992, 997 (D.C. Cir. 1990)). The United States District Court for the District of Columbia summarized the reason for exceptions as follows: "[u]nderlying all of these exceptions is the assessment that 'resort to extra-record information [is necessary] to enable judicial review to become effective.'" *National Mining Association v. Jackson*, 856 F. Supp. 2d 150, 157 (D.D.C. 2012) (quoting *Calloway v. Harvey,* 590 F. Supp. 2d 29, 38 (D.D.C. 2008)).

Finally, when an entity challenges an agency decision as "contrary to constitutional right," pursuant to 5 U.S.C. § 706(2)(B), the reviewing court "should make 'an independent assessment of a citizens' claim of constitutional right.'" *Tafas*, 530 F. Supp. 2d at 802 (quoting *Porter v. Califano*, 592 F.2d 770, 780 (5th Cir. 1979)). However, "even where plaintiffs have asserted constitutional claims, 'wide-ranging discovery is not blindly authorized at a stage in

which an administrative record is being reviewed.'" *Id.* (quoting *Puerto Rico Public Housing Admin. v. United States Dep't of Housing and Urban Development*, 59 F. Supp. 2d 310, 327 (D.P.R. 1999)).

B. The Court Will Allow Limited Discovery Given This Atypical Administrative Procedure

Regardless of which First Amendment standard ultimately applies, the Court finds a period of limited discovery justified in this case. Defendants have sufficiently suggested that the Administrative Record might be "so deficient as to preclude effective review,"[22] of the 2017 Modified Advisory Opinion process, such that the Court will allow discovery regarding the nature of the advisory opinion process, *i.e.* whether it constitutes a negotiation or a mandate.[23] Patient Services's "claim of constitutional right" and both parties' agreement (albeit only as to harm), that the Administrative Record is "incomplete" also support limited discovery. *See Tafas*, 530 F. Supp. 2d at 794, 802.

Although, unlike many of the cases cited above, the government agency, not the plaintiff, seeks discovery, the Court finds limited discovery warranted given the baseline dispute as to how to assess this First Amendment challenge. The Administrative Record must also be expanded to show harm. Finally, without converting requests for discovery into an enforcement action, Defendants should be allowed to inquire about Patient Services's "truthful, non-misleading, and lawful communications with donors, prospective donors, and their 'affiliates.'" (Reply 9; Resp. 8; Compl. ¶¶ 129, 136, 143–44.)

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[22] *Hill Dermaceuticals, Inc. v. F.D.A.*, 709 F.3d 44, 47 (D.C. Cir. 2013).

[23] Patient Services also contends that Defendants violated the unconstitutional conditions doctrine by requiring it to accept the Three Certifications to maintain a favorable Advisory Opinion. Because the Court cannot yet determine which First Amendment standard applies at this stage of the litigation, the Court will not address whether the unconstitutional condition doctrine applies in this decision.

Discovery here is especially warranted because Patient Services must prove standing. Both parties recognize that the Administrative Record does not, and could not, include the post-decision information necessary to determine what harm Patient Services suffered. Defendants must be allowed to assess any applicable injury, which goes to the heart of this Court's jurisdiction. Patient Services's offer to submit a declaration to prove such harm does not comport with standard adversarial practices that undergird the interest of justice.

Discovery will be reciprocal. After the limited period of discovery, each party will have an opportunity to take a position on whether and how the record should be supplemented. The parties may disagree as to whether, or to what degree, the record should be supplemented. To the extent disagreement exists, the parties must specifically identify the scope and nature of the factual dispute.

Once a final record is established, the parties will each be allowed to file briefs as to whether this Court has jurisdiction over the case. To the extent standing is established, the parties shall also address which First Amendment standard this Court should utilize, citing pertinent aspects of the finalized Administrative Record. A review of the 2017 Modified Advisory Opinion will flow from the decisions made on these preliminary issues.

III. Conclusion

Having reviewed the parties' filings and the applicable laws and regulations, the Court will grant the Motion, with limitations. (ECF No. 35.) No later than close of business February 8, 2019, the parties shall submit a joint discovery plan which delineates the scope and duration of discovery going forward. This plan shall serve to "secure the just, speedy, and inexpensive determination" of this discovery period. Fed. R. Civ. P. 1. To the extent the parties believe that

the appointment of a Special Master would support those goals, they may submit a joint motion for doing so and include any justification in their joint discovery plan.

Also no later than February 8, 2019, the parties shall submit a joint briefing schedule that will follow discovery. The Court will hold a status hearing after the stipulated plans have been filed.

An appropriate Order shall issue.

/s/
M. Hannah Lauck
United States District Judge

Date: 1/18/2019
Richmond, Virginia